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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,803	09/19/2003	Unchalee Kositprapa	141-424	3478

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HEDMAN & COSTIGAN P.C.
1185 AVENUE OF THE AMERICAS
NEW YORK, NY 10036

EXAMINER	
FITZGERALD, MARC C	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 11/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/664,803	KOSITPRAPA ET AL.	
	Examiner	Art Unit	
	Marc C. Fitzgerald	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/3/06; 12/29/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

Receipt is acknowledged of correspondences received on 2 June 2006 in the matter of U.S. Patent Application No. 10/664,803. Claims included in the prosecution are 1-31.

Claim Rejection – Nonstatutory Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 4-6 and 8-10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 20, and 33-40 of copending Application No. 11/094493. Although the conflicting claims are not identical, they are not patentably distinct from each other because both copending

applications describe a controlled release dosage form comprising first and second active agents wherein the agents are biguanides and thiazolidinediones and are release at the same T_{max}.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejection(s) – 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Step (b) in claims 1 fails to set forth the "meets and bounds" of the claimed invention. The specification and the claims seceding claim 1 indicate that the seal coat around the control release is an optional step. As written the claim is indefinite because it cannot be ascertained whether the seal coat is a required or optional step, thus the applicant has failed to set forth the meets and bounds of the claim. See MPEP § 2173.05(d). In light of the specification and claims 2-10, step (b) in claim 1 is read as an optional step.

Claims 1-5, 7-15, 17-25, and 27-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term " thiazolidinedione derivative" in claims 1-5, 7-15, 17-25, and 27-30 is a relative term which renders the claims indefinite. The term " thiazolidinedione derivative" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. On instant pages 5-6 of the specification, last line page 5 bridging page 6, use of the language "These include, but are not limited to..." does not provide a standard for ascertaining the requisite degree.of the term "thiazolidinedione derivative." Its use in the claims is therefore indefinite.

Claims 7, 17, and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. This claim is an omnibus type claim because the claim language "substantially free" is indefinite and not supported by the specification. On instant pages 6-7, the specification indicated that the composition does contain gelling or swelling polymers.

Claim Rejection(s) – 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Publication No. US 2006/0204578 A1 to Vergez et al.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The instant application claims a pharmaceutical dosage form having two active drugs wherein the dosage form comprises a controlled release core comprising an antihyperglycemic drug and at least one pharmaceutically acceptable excipient; a seal coat; and an immediate release coating comprising thiazolidinedione. At [0067], [0082], Fig. 10, and claims 1, 32, 49, US '578 teaches a controlled release osmotic dosage form comprising two different active agents, i.e., two different antidiabetic agents such as biguanides and thiazolidinediones, wherein the dosage from comprises a membrane surrounding a bilayered core, and the core comprising an inner nucleus comprising the first active agent and a second layer surrounding the inner nucleus comprising a

different second active agent. At [0043] and [0063], Vergez explicitly teaches an optional embodiment wherein the tablet comprises an external coating disposed on the outside of the osmotic device comprising one or more active agents for immediate delivery to the environment of use. Further at [0149] and claim 50, Vergez teaches that antidiabetic agents include thiazolidinediones such as rosiglitazone, pioglitazone, and troglitazone and biguanidines such as metformin. The synergistic effect of biguanidine and thiazolidinedione for treating diabetics and diabetic conditions is well known in the art. According to the *Physician's Desk Reference*, effective dosage amounts of a thiazolidinedione such as pioglitazone is known to be 15, 30, and 45 mg. The effective dosage for a biguanidines such as metformin is known to range from 500 to 2550 mg. One of ordinary skill in the art at the time of the invention would have been motivated to include the antidiabetic with the smaller dosage (lower MW) in the outer layer since it is intended for immediate release and has a quicker dissolution profile. Likewise, the artisan would have been motivated to include the larger dosage (higher MW) antidiabetic in the core since it has slower dissolution profile and would take longer for it to erode or dissolve. Hence the reference makes obvious instant claim 1, 2, 4-7, 11, 12, 14-17, 21, 22, 24-27.

Vergez teaches the various limitations of the instant claims with regard to the tablet features such as the antihyperglycemic drug, binding agent, absorption enhancer, lubricant, seal coat, semipermable membrane, polymer, flux enhancer, plasticizer, surfactanct, pore-forming agents, and passageways at [0104-0109, 0121, 0122, 0126, 0133, 0134]. Vergez does not teach the % as claimed in the instant application.

However, these percentages can be obtained through routine experimentation. The artisan would have been motivated to determine these amounts to get the maximum efficacy of the dosage form. Results obtainable through routine experimentation are not patentable over the art. Hence the reference makes obvious instant claims 3, 13, and 23.

At [0069], Vergez teaches that the relative amounts of each active agent released at a given time can be controlled by changing the location of the passageway(s) in the wall (3). For example, if the first (4) and second (6) compositions have the same release properties and the device includes the sole passageway (5) centered on the composition (4), the device (1) will release a major portion of the first composition (4) before it releases any of the composition (6). If the first (4) and second (6) compositions have the same release properties and the device includes the sole passageway (5) in communication with the composition (4) and proximal but not in direct communication with the composition (6), the device (1) will release only a minor portion of the first composition (4) by the time it begins to release the second composition (6).

Further at [0098], Vergez teaches in a particular embodiment that the controlled release dosage form will provide effective amounts of active agent for a period of not less than 18 hours and not more than 30 hours, or not less than 20 hours and not more than 28 hours, or not less than 22 hours and not more than 24 hours. Vergez further teaches that the artisan of ordinary skill will understand that administration of a single unit dose period of time may be insufficient to maintain therapeutic plasma levels of

active agent for up to 24-30 hours and that multiple unit doses administered over an equal number of days may be required to maintain therapeutic plasma levels of active agent for up to 24-30 hours. The determination of the time release quantities in claims 8-10, 18-20, and 28-30 are well within the level of one of ordinary skill in the art. The artisan would have motivated at the time of the invention to determine the maximum release times to determine optimum efficacy of the drugs being administered. Hence, the reference makes obvious instant claims 8-10, 18-20, and 28-31.

Pertinent Arts

U.S. Patent No. Application Nos. 6,342,249 B1 and 6,342,249 B1 both to Wong et al. are made of record but not relied upon because it teaches a dual controlled release osmotic dosage form comprising first and second active agents wherein the agents are biguanides and thiazolidinediones.

Correspondences

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marc C. Fitzgerald whose telephone number is (571) 272-8510. The examiner can normally be reached between 9:30 AM - 6:30 PM (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marc C. Fitzgerald
Art Unit –1615

6 November 2006

MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600